4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0145]

Agency Information Collection Activities; Proposed Collection; Comment Request; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey entitled "Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities." The data collection will obtain knowledge of State and local capacities including food safety defense staffing and expertise, laboratory capacities, and information systems to support food and feed safety and defense.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Improving Food Safety and Defense Capacity at the State and Local Level: Review of State and Local Capacities--(OMB Control Number 0910--New)

The Food Safety Modernization Act (FSMA) (Public Law 111-353) states that a review must be conducted to assess the State and local capacities to show needs for enhancement in the areas or staffing levels, laboratory capacities, and information technology systems. This mandate is referenced again in FSMA section 110 stating that a review of current food safety and food defense capabilities must be presented to Congress no later than 2 years after the date of enactment (enactment date January 4, 2011). In order to facilitate this review, this team must distribute a survey to State and local health and agriculture agencies. In doing so, this team will be able to analyze the gaps and trends to occur at these respective levels which will allow FSMA counterparts to develop ways to enhance food safety and food defense. In developing these strategies, FDA will be able to work with other Federal Agencies to improve and expand food safety and defense to ultimately reach a state of an integrated food safety system.

FDA will conduct the survey electronically which allows FDA to conduct streamlines analysis while creating a low-burden, user-friendly environment for respondents to complete the

survey. Once the results have been tabulated, a report will be generated and given to FSMA section 110 to present to Congress as well as FSMA section 205(c)1 to develop the strategies to leverage and enhance current State and local capacities.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Current State and local government employees	1,400	1	1,400	1	1,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This survey is slated to be a one-time survey. Through testing on six FDA employees who were formerly State employees, the survey development team has come to the conclusion that it should take no longer than 1 hour for the 1,400 current State and local government employees to complete the survey. FDA is requesting this data collection burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4289 Filed 02/23/2012 at 8:45 am; Publication Date: 02/24/2012]